REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks.

I. CLAIM STATUS & AMENDMENTS

Claims 1-9 were pending in this application when last examined.

Claims 2, 3, 5, 6, 8 and 9 have been examined on the merits, and stand rejected.

Claims 1, 4 and 7 are withdrawn as non-elected subject matter.

II. FOREIGN PRIORITY CLAIM

Kindly acknowledge the claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). As noted in item 1 in the Official Communication dated September 10, 2001, the priority document was submitted to the PTO by the International Bureau.

III. REJECTIONS UNDER 35 U.S.C. §§ 101, 112, FIRST PARAGRAPH, UTILITY

Claims 2, 3, 5, 6, 8 and 9 were rejected under 35 U.S.C. § 101, as lacking utility. Consequently, claims 2, 3, 5, 6, 8 and 9 were also rejected under 35 U.S.C. § 112, first paragraph, on the basis that specification lacks an enabling disclosure for how to use the claimed invention. See pages 2-5 of the Office Action.

This rejection is respectfully traversed for the reasons set forth in section III on pages 6-9 of the response filed March 23, 2004 and for the following reasons.

Contrary to the position taken in the Action, the specification discloses numerous specific asserted utilities. An asserted utility is an explicit statement of "why the applicant believes that the invention is useful." M.P.E.P. § 2107.02, A. Such statements will usually explain the purpose of how the invention may be used. Ibid. In this regard, the specification explicitly discloses numerous specific asserted utilities for the claimed polynucleotide and the nuclear protein it encodes as noted below:

1. the use of the polynucleotide of SEQ ID NO:2 as a probe for the diagnosis of various diseases, such as cancer (Specification, page 1, lines 13-14);
2. the use of the polynucleotide of SEQ ID NO:2 as a source for gene therapy (Specification, page 1, lines 13-14);
3. the use of the polynucleotide of SEQ ID NO:2 in expression vectors to produce the human nuclear protein of SEQ ID NO:1 (Specification, page 1, lines 13-14);
4. the use of the human nuclear protein of SEQ ID NO:1 for the diagnosis and therapy of various diseases, including cancer (Specification, page 1, lines 11-12 and page 15, lines 6-10); and
5. the use of the human nuclear protein of SEQ ID NO:1 for the generation of antibodies with diagnostics and research application (Specification, page 1, 11-12 and page 15, lines 6-10).

The above-noted utilities, which are explicitly disclosed in the specification, amount to specific asserted utilities despite the characterization otherwise in the Office Action. The Office erroneously indicates that such uses are not specific asserted utilities, because the Applicants allegedly fail to provide specific knowledge as to the function of the claimed polynucleotide of SEQ ID NO:1 or the protein it encodes. See Office Action, page 3. However, notwithstanding that the above-noted utilities are specific asserted utilities, even if they were not characterized as such, it is respectfully submitted that they also provide a basis for a credible and substantial well-established utility.

An invention has a well established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process) in view of the knowledge in the art, and (ii) the utility is specific, substantial and credible. M.P.E.P. § 2107.02, II, B; *Guidelines for Examination of Applications for Compliance With the Utility Requirement*, 66 Fed. Reg. 1097, 1098 (Jan. 5, 2001).

A "substantial" utility defines a "real world" use. Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. M.P.E.P. § 2107, I. As a general

matter, a reasonable correlation between the evidence presented and the asserted utility is sufficient to establish a credible and substantial utility. M.P.E.P. § 2107.03, I.

An assertion of utility is credible if it is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided. In other words, it is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. M.P.E.P. § 2107.02, III, B.

In the instant case, the disclosed use is substantial and credible. The specification discloses that the claimed polynucleotide encodes a novel human nuclear protein consisting of 704 amino acids, which contains a WW domain, and which exists in cellular nuclei. The specification further discloses that human nuclear proteins have well established functions, such as transcription factors, splicing factors, intranuclear receptors, cell cycle regulators, tumor suppressors, etc. Specification, page 1, lines 24-30. The specification also discloses that the protein of the instant invention shares high homology with known human nuclear proteins. The specification also establishes that the human nuclear protein encoded by the claimed polynucleotide contains a WW domain, and that it is well established that WW domains are contained in the cytoskeleton system. The specification indicates that the claimed protein is involved in the signal transduction, as well as in ubiquitin-protein ligase in the protein degradation system and in a transcription activator. Specification, page 2, lines 5-20, page 10, lines 20-23. The Applicants also found that the protein encoded by the claimed polynucleotide binds the c-terminal domain of RNA polymerase and is involved in mRNA synthesis.

Based on such findings, those skilled in the art would immediately recognize that the claimed polynucleotide sequence (SEQ ID NO: 2) and the human nuclear protein it encodes (SEQ ID NO: 1) have "real world" value as markers to assess signal transduction and mRNA synthesis in healthy and/or diseased cells, and/or as diagnostic agents and medicaments for diseases involving signal transduction and mRNA synthesis. For instance, the invention is useful to assess mRNA synthesis given its disclosed binding capacity to the c-terminal domain of RNA polymerase. See page 7, lines 3-5 of the disclosure. It is noted that the specification also discloses antibodies prepared from the protein encoded by the claimed polynucleotide. Such

antibodies would also be useful as tools to monitor signal transduction and mRNA synthesis in healthy and/or diseased cells.

Laboratory markers and diagnostic antibodies are well known and have widely established uses in the biotechnology industry. Likewise, the use of proteins in assays to detect the presence or absence of disease is also well known. Accordingly, such uses are credible based upon the disclosure and the knowledge in the art.

It is noted that M.P.E.P. § 2107(I) indicates that an assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular condition defines a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. Given that such use is analogous to the example described in the M.P.E.P. as a credible utility, it is evident that at least one of the above-discussed utilities is credible. As such, it would be inconsistent to maintain that the claimed invention lacks utility. Moreover, no evidence has been presented to contradict such utility. Accordingly, the skilled artisan, upon reading the disclosure, would immediately recognize this use as credible.

Thus, the specification discloses a credible and substantial "specific asserted utility" and a credible and substantial "well-established utility" for the claimed polynucleotide sequence of SEQ ID NO:2 encoding the novel human nuclear protein of SEQ ID NO:1 having a WW domain.

Again, it is noted that the ***threshold of utility is not high*** and that asserted utilities are ***presumed true***. M.P.E.P. § 2107.01. The Office has failed to overcome this presumptive truth of the asserted specific utilities, because it has not shown by a ***preponderance of evidence*** that it is ***more likely than not*** that the disclosed and well-established utilities would be considered false by a person of ordinary skill. M.P.E.P. § 2107.01. Again, no evidence or arguments have been presented to contradict the specific asserted and well-established utilities discussed above. In other words, the Office has not shown by a preponderance of evidence that it is more likely than not that such utilities would be considered false by a person of ordinary skill in the art.

In the absence of any scientific evidence or apparent reasons why the claimed compounds do not possess the disclosed specific utilities, the allegation of utility in the Specification must be accepted as correct. *In re* Kamal, 158 U.S.P.Q. 320, 323 (C.C.P.A. 1968). Certainly, the Office

has not provided evidence that ***all*** the asserted specific utilities and well established utilities would be reasonably doubted, are inherently unbelievable or involve implausible scientific principles.

Instead, the rejection relies upon the assertion that despite the high homology to known human nuclear protein, "homology does not necessarily correlate to function" (sentence bridging pages 3-4 of the Office Action) and the activity of the protein encoded by SEQ ID NO:2 was never established (Office Action, page 4). The rejection also relies on the Chen reference as allegedly establishing that no function has been established for a protein with WW domains. However, such reasoning does not diminish the use of the claimed invention to assess mRNA synthesis or signal transduction, which are two very important intracellular functions for the general cellular activities regardless of a disease condition or an ultimate function of the protein. Thus, such protein could still be used to assess mRNA synthesis and signal transduction to monitor cellular development and activities. Clearly, such use is credible and has real world application.

Thus, in view of the above, the utility and enablement rejections under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph, are untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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